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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/887,505 07/02/97 KILKUSKIE

R HYZ-040CIP

HALE AND DORR
60 STATE STREET
BOSTON MA 02109

HM22/0518

EXAMINER

TAYLOR, J

ART UNIT	PAPER NUMBER
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1655

22

DATE MAILED:

05/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
08/887,505	KILKUSKIE ET AL.	
Examiner	Art Unit	
Janell Taylor Cleveland	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 December 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 35-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 12/22/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/887,505 is acceptable and a CPA has been established. An action on the CPA follows.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Election/Restriction

2. Applicant is reminded of their election with traverse of Group I, claims 1-31 in Paper No. 9. The restriction was made final in the last Office Action and was modified to incorporate claims 32-34 as well.

Claim Objections

3. Claim 7 is objected to because of the following informalities: There is no SEQ ID number given for one of the sequences listed. Appropriate correction is required.

4. Claim 34 is objected to under 37 CFR 1.75(c) as being in improper form because it is a multiple dependent claim, but does not refer to claims 32 and 1 or 2 in the

alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. Claims 1, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 25, 27, 28, 29, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because it cannot be determined what oligonucleotides are encompassed in the claims. Specifically, it is unclear whether the claimed oligonucleotides require only one sequence from either of the two recited groups of SEQ ID Nos, or require a sequence from both recited groups. Clarification is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claim 1 rejected under 35 U.S.C. 102(e) as being anticipated by Kamada et al. (EP 0469342 A2).

Claim 1 is drawn to a synthetic oligonucleotide complementary to a portion of the 5' untranslated region of Hepatitis C virus having SEQ ID NO 2. Kamada et al. disclose

SEQ ID NO: 15 used as a primer to detect Hepatitis C virus. SEQ ID NO: 15 is exactly the same as SEQ ID NO: 2 in the instant application (see pg. 25, SEQ ID NO: 15.)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2-6, 8-20, 25, 27, 28, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being disclosed by Hogan, et al in US Patent 5,424,413 in view of Maertens et al. (US Patent 5,846,704).

These claims are drawn to an oligonucleotide comprising a sequence complementary to at least two non-contiguous regions of an HCV mRNA or genomic RNA.

Hogan discloses a nucleic acid hybridization probe having at least one nucleic acid strand which has at least two separate target specific regions that hybridize to a target nucleic acid sequence. (See Abstract, Drawing 4A). This patent also discloses the use of modified oligonucleotides, as well as therapeutic applications for oligonucleotides.

This patent does not disclose an HCV messenger or genomic RNA.

Maertens et al. disclose as their invention probes targeting sequences from the 5' untranslated region of HCV. (See Abstract).

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One of ordinary skill in the art would have been motivated to target the probe of Hogan et al to an HCV messenger or genomic RNA because Maertens et al disclosed the importance of detecting HCV nucleic acids. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

10. Claims 7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. in view of Maertens et al. and further in view of Seki et al.

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NO: 47 and 160.

The teachings of Hogan et al. and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequence of the claims.

Seki et al. disclose an oligonucleotide (SEQ ID NO: 6) identical to instant SEQ ID NO: 47. Seki et al also disclose an oligonucleotide (SEQ ID NO: 229) nearly identical to instant SEQ ID NO: 160.

One of ordinary skill in the art would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the method as discussed above because these would have clearly been useful in detecting HCV nucleic acids. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

11. Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. in view of Maertens et al. and further in view of Cha et al.

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NOS: 122 and 117.

The teachings of Hogan and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequence of the claims.

Cha et al. disclose an oligonucleotide (SEQ ID NO: 15) nearly identical to instant SEQ ID NO: 122. Seki et al. also disclose an oligonucleotide (SEQ ID NO: 39) nearly identical to instant SEQ ID NO: 117.

One of ordinary skill in the art at the time of the invention would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the method as discussed above because these would have clearly been useful in detecting HCV nucleic acids. It would have been prima facie obvious to one of ordinary skill in the art at the

Conclusion

12. Applicant is again reminded that THIS ACTION IS MADE FINAL.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor whose telephone number is (703) 305-0273. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1655 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor

01/11/01


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
5/12/01